PATENT COOPERATION TREATY

WO 2006/072947
PCT/IL2006/000015

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

G.E. EHRLICH (1995) LTD.
11 Menachem Begin Street
52521 Ramat Gan
ISRAËL

Date of mailing *(day/month/year)* 16 August 2006 (16.08.2006)	
Applicant's or agent's file reference 30480	IMPORTANT NOTIFICATION
International application No. PCT/IL2006/000015	International filing date *(day/month/year)* 04 January 2006 (04.01.2006)
International publication date *(day/month/year)* 13 July 2006 (13.07.2006)	Priority date *(day/month/year)* 04 January 2005 (04.01.2005)
Applicant DUNE MEDICAL DEVICES LTD. et al	

1. By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. *(If applicable)* The **letters "NR"** appearing in the right-hand column denote **a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau** under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

3. *(If applicable)***An asterisk (*)** appearing next to a date of receipt, in the right-hand column, denotes **a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b)** (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
04 January 2005 (04.01.2005)	60/641,081	US	17 January 2006 (17.01.2006)
29 March 2005 (29.03.2005)	60/665,842	US	10 February 2006 (10.02.2006)

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 30480	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IL2006/000015	International filing date *(day/month/year)* 04 January 2006 (04.01.2006)	Priority date *(day/month/year)* 04 January 2005 (04.01.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DUNE MEDICAL DEVICES LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 31 July 2007 (31.07.2007)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
GAL EHRLICH
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RAMAT GAN, ISRAEL 52521

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	21 JUN 2007
Applicant's or agent's file reference 30480	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL06/00015	04 January 2006 (04.01.2006)	04 January 2005 (04.01.2005)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61B 5/05**(2006.01)
USPC: 600/407

Applicant

DUNE MEDICAL DEVICES LTD.

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	24 May 2007 (24.05.2007)	Eleni M Mantis-Mercader Telephone No. 1-800-786-9757

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL06/00015

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL06/00015

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 5-9,11-12,32-35,44-58,63-68	YES
	Claims 1-4,10,13-31,36-43,59-62,69	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-69	NO
Industrial applicability (IA)	Claims 1-69	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

. **Supplemental Box**
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-4, 10, 13-31, 36-43 and 69 lack novelty under PCT Article 33(2) as being anticipated by Bambot et al. Bambot et al. disclose an endoscope that uses optical fibers to serve as a nonirradiative electromagnetic sensor (column 10, lines 27 through column 11, line 14). They disclose that their invention can be used in various situations, such as in vivo detection of diseased tissues (i.e cancerous tissues) (column 3, lines 60-67). Their invention includes a processor (44), as well as a frequency synthesizer (46) and a detector (56). See Figure 1. The endoscope is introduced into a natural lumen or a cavity of a patient's body, such as an oral cavity, a nostril, etc. (column 4, lines 1-18). Their endoscope includes an optical fiber bundle (54) that serves as a communication line (column 10, lines 27-36). The endoscope further includes a long body portion that may be inserted into a body of the patient (i.e. intracorporeal portion) as well as a hande (i.e. extracorporeal portion) that can be used for positioning the endoscope (column 10, lines 37-54). They further disclose that a device (i.e. second instrument) may be positioned on a distal end of the endoscope (column 10, lines 37-44). The device may be used to remove tissue samples from a patient (i.e. biopsy), introduce a dose of medication to a target tissue, or be used to deliver therapeutic radiation (column 10, lines 37-44). Bambot et al. further disclose a method using their invention for tissue characterization (column 11, lines 46-60).

Claims 5-7, 44-45, and 47-50 lack an inventive step under PCT Article 33(3) as being obvious over Bambot et al. in view of Bladen et al. Bambot et al. do not disclose that the nonirradiative electromagnetic sensor may be removed and replaced with another instrument. Further, they do not disclose that their endoscope further includes a catheter that can extend beyond a distal-most end of the endoscope and can be manipulated independently of the endoscope. Bladen et al. disclose an endoscope wherein a sensor can be placed inside the biopsy channel of an endoscope (pg.6-7, paragraphs [0102]-[0103]). They further disclose that the endoscope passes the sensor down the tip of the biopsy channel until it reaches the tip of the endoscope (pg. 7, paragraph [0106]). The sensor is encapsulated within a hollow tubular catheter which is routinely used with endoscopes (pg. 7, paragraph [0106]). The catheter can then be withdrawn (pg. 7, paragraph [0106]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include with the endoscope of Bambot et al. a removable sensor, as well as a catheter. The motivation for doing so would have been to provide information about the path of the endoscope and catheters are routinely used with endoscopes, as taught by Bambot et al. (pg. 6, paragraph [0101] and pg. 7, paragraph [0106]).

Claims 8-9 and 32 lack an inventive step under PCT Article 33(3) as being obvious over Bambot et al. in view of Nakaichi et al. Bambot et al. do not disclose that the intracorporeal portion further includes an optical channel for an optical instrument, nor that that the optical instrument is configured to observe the nonirradiative electromagnetic sensor. Nakaichi et al. disclose an endoscope for optically

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

observing the body cavity of the patient (column 1, lines 7-17). They further disclose that an image transmitting optical fiber bundle and an illumination light transmitting optical fiber bundle are incorporated within the insertion unit of the endoscope (i.e. intracorporeal portion) (column 6, lines 44-56). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included an optical channel for an optical instrument, and have the optical instrument configured to observe the nonirradiative electromagnetic sensor. The motivation for doing so would have been to be able illuminate the cavity and enable an image of the body cavity to be observed as taught by Nakaichi et al. (column 1, line 65 through column 2, line 6).

Claims 11-12 and 33-35 lack an inventive step under PCT Article 33(3) as being obvious over Bambot et al. in view of Nevo et al. Bambot et al. do not disclose that the second instrument is selected from the group consisting of an optical sensor, an x-ray sensor, an ultrasound sensor, an MR sensor, etc., nor that the second instrument is configured to sense the nonirradiative electromagnetic sensor. Nevo et al. discloses that their invention includes the use of a separate set of tracking coils for tracking purposes (i.e. electromagnetic sensor), and a separate set of imaging coils for imaging purposes (i.e. MR sensor) (pg. 6, paragraph [0076], pg.3, paragraph [0029]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include in the invention of Bambot et al. a second instrument selected from group listed above. The motivation for doing so would have been to enable the instrument to image selected areas within the body cavity, as taught by Nevo et al. (pg.3, paragraph [0028]).

Claim 46 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Nevo et al. Bambot et al. in view of Bladen et al. do not disclose that the sensor for tissue characterization is selected from the group consisting of an optical sensor, an x-ray sensor, an MR sensor etc. Nevo et al. disclose that their invention includes the use of a separate set of tracking coils for tracking purposes (i.e. electromagnetic sensor), and a separate set of imaging coils for imaging purposes (i.e. MR sensor) (pg. 6, paragraph [0076], pg.3, paragraph [0029]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include in the invention of Bambot et al. a sensor selected from the group listed above. The motivation for doing so would have been to enable the instrument to image selected areas within the body cavity, as taught by Nevo et al. (pg.3, paragraph [0028]).

Claims 59-62 lack novelty under PCT Article 33(2) as being anticipated by Nevo et al. Nevo et al. disclose an endoscopic examining apparatus that has an integrated imaging and tracking capability (pg. 3, paragraph [0026]). The tracking system uses miniature sensors that senses electromagnetic fields generated by an MR scanner (pg. 3, paragraphs [0024] and [0025]). The probe has a hollow construction in which a guidewire may be inserted for injection of contrast material, biopsy, or for other diagnostic or interventional procedures that may be required (pg. 4, paragraph [0038]). They further disclose that their invention includes the use of a separate set of tracking coils for tracking purposes (i.e. electromagnetic sensor), and a separate set of imaging coils for imaging purposes (i.e. MR sensor) (pg. 6, paragraph [0076], pg.3, paragraph [0029]).

Claims 51-58 and 63-68 lack an inventive step under PCT Article 33(3) as being obvious over Nevo et al. in view of Bambot et al. Nevo et al. do not disclose that a second instrument is inserted, mounted on a second communication line, intracorporeally, along the guide wire. They also do not disclose that the instrument can be a biopsy instrument, configured for localized surgery, or for dispensing medication. Bambot et al. disclose that a separate device (i.e.instrument) may be included with the endoscope and used to remove tissue samples from a patient, introduce a dose of medication, or emit therapeutic radiation (column 10, lines 37-44). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include with the endoscope a second instrument. The motivation for doing so would have been to be able to perform multiple functions, as taught by Bambot et al. (column 10, lines 37-44).

Claims 1-69 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.